APPENDIX B
Marked-Up Copy Of Substitute Specification
Application Serial No. 10/530,087
Docket No. 8932-1091-999

BONE FIXATION DEVICE[1]

CROSS-REFERENCE TO RELATED APPLICATIONS[2]

This application is the United States National Stage application of PCT/CH02/00550, filed October 3, 2002.[3]

FIELD OF THE INVENTION[4]

The invention relates to a bone fixation device[5] ~~of the introductory portion of claim 1.~~[6], in particular for fixing fractures at the proximal femur.[7]

BACKGROUND OF THE INVENTION[8]

In the case of fractures at the proximal femur, especially in the case of pertrochantric fractures, medullary pins are frequently brought in to the femur for immobilizing bone fragments. Moreover, at the proximal end of the medullary pin, a bone plate is mounted, by means of which the forces and moments, acting on the head of the hip joint and the greater trochanter, can be transferred to the medullary pin.[9]

~~The US patent~~[10]United States Patent No.[11] 5,356,410 [12]~~of PENNIG~~[13]to Pennig[14] discloses a [15]~~genetic~~[16]generic[17] device, for which a perforated bone plate, coming to rest on the greater trochanter, is fastened by means of a screw connection to the proximal end of a medullary pin without transverse boreholes. It is a disadvantage of this known device that the bone plate is disposed diametrically to the neck of the femur and protrudes distantly beyond the hip screws, which can be connected to the bone plate for immobilizing fixing the head of the hip joint.[18]

SUMMARY OF THE INVENTION[19]

The [20]present [21]invention [22]~~is to provide a remedy here~~[23]remedies this problem[24]. It is an object of the invention to create a device for bone fixation, especially at the proximal femur, which, on the one hand, transfers an existing muscle force over the hip screw as well as over the bone plate directly to the medullary pin and, on the other, transfers forces, acting on the head of the hip joint, not onto the bone plate and, with that, directly on to the shaft of the femur. Furthermore, the muscles, especially the vastus

lateralis, the gluteaus minimus, the piriformis and the gluteaus medius and ligaments are not affected distally by the extension of the bone plate.[25]

~~Pursuant to the invention, this objective is accomplished with bone fixation device, which has the distinguishing features of claim 1.~~[26]

The inventive bone fixation device comprises essentially an intramedullary pin and a bone plate, which is intended to lie in contact with the greater trochanter and is disposed at the proximal end of the medullary pin, the latter, in its proximal half facing the proximal rear end, having at least one transverse borehole passing through it for accommodating a hip screw and the bone plate terminating proximally above this transverse borehole.[27]

The advantages, achieved by the invention, can be seen to lie essentially therein that, due to the inventive device,[28]

- a resistance or counter-moment can be offered to the muscle forces, which act on the greater trochanter, especially in the case of fractures of type 31 A3.2 of the AO (Association for Osteosynthesis) classification; [29]
- forces acting on the head of the hip joint, especially the force component acting parallel to the neck of the femur[30,31] can be transferred to the medullary pin; and[32]
- the muscles and ligaments, surrounding the greater trochanter, are not affected.[33]

The length L of the bone plate, measured parallel to the longitudinal axis of the medullary pin, preferably is between 2 mm and 40 mm.[34]

In a preferred embodiment of the inventive device, the bone plate comprises a distally angled tab, the center of gravity of which, if projected into a cross-sectional area orthogonal to the longitudinal axis of the medullary pin, lies on a radius, which encloses an angle [35]~~β~~[36]β[37] of between 0° +100° and preferably of between +40° and +50°. These ranges for the angle [38]~~β~~[39]β[40] are for the embodiment of the inventive device at the right

femur. For the embodiment of the inventive device, which can be used for the left femur, the angle [41]~~β~~[42]β[43] is between 0° and -100° and preferably between -40° and -50°. This arrangement permits the bone plate to be passed past muscles and ligaments disposed at the greater trochanter.[44]

In a further embodiment of the inventive device, a further tranverse borehole for accommodating a locking screw passes through the distal half of the medullary pin facing the tip of this pin. By these means, the advantage can be attained that the load on the proximal zone of the femur is relieved and the absorption of this load is taken over by the medullary pin. Instead of the transverse borehole, transverse grooves are also possible, which are disposed transversally to the longitudinal axis of the medullary pin at the tip of latter.[45]

In a different embodiment of the inventive device, the medullary pin and the bone plate are constructed in one piece, so that the device to be implanted comprises fewer individual parts.[46]

In yet another embodiment of the inventive device, the tab is constructed in such a manner, that it is at a distance from the medullary pin and, viewed parallel to the longitudinal axis, is passed around the medullary pin with an angle [47]~~α~~[48]α[49], the angle [50]~~α~~[51]α[52] being between 10° and 200° and preferably between 20° and 40°.[53]

~~Further advantageous developments of the invention are characterized in the dependent claims.~~[54]

BRIEF DESCRIPTION OF THE DRAWINGS[55]

The invention and further developments of the invention are explained in even greater detail [56]~~in the following by means of~~[57]below with reference to[58] partially diagrammatic representations of several examples[59]~~. In the drawing,~~[60], where: [61]

~~Fig~~[62]FIG[63] 1[64] shows a section through an embodiment of an inventive device at the proximal femur;[65]

~~Fig~~FIG. 2 shows an exploded representation of the preferred embodiment of the inventive device and

~~Fig~~FIG. 3 shows a section of the distal portion of the medullary pin in one embodiment of the inventive device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In ~~Fig~~FIG. 1, the medullary pin 1, introduced into the medullary space of a femur, is shown together with a bone plate 10, which is disposed at the greater trochanter. The medullary pin 1 has a longitudinal axis 17 and a proximal half 7 and a distal half 4 coaxial with this longitudinal axis 17. The bone plate 10 is angled distally and comprises a part, which is disposed transversely to the longitudinal axis 17 of the medullary pin 1, where the bone plate 10 is fastened by means of a screw connection 16 to the proximal rear end 3 of the medullary pin 1, and a tab 22, which extends towards the distal tip 2 of the medullary pin 1 and is provided with perforations 11. Furthermore, in its proximal half 7, the medullary pin 1 comprises a proximal transverse borehole 6 and a second transverse borehole 8, both of which are intended to accommodate hip screws 30~~,~~ and 31. The transverse boreholes 6~~,~~ and 8 pass through the medullary pin transversely to the longitudinal axis 17. The bone plate 10 ends proximally above the proximal transverse borehole 6. In the distal half 4 of the medullary pin 1, a transverse borehole 5 is disposed also transversely to the longitudinal axis 17 of the medullary pin 1 at the distal tip 2 of the latter. A locking screw 20 is introduced into this distal transverse borehole 5 and screwed into the femur.

In ~~Fig~~FIG. 2, the proximal half 7 of the medullary pin 1 and the bone plate 10 are shown. The bone plate 10 comprises a part, which is disposed transversely to the longitudinal axis 17 of the medullary pin 1 and a tab 22, angled distally, with two petals 23; 24, which are aligned towards the distal tip of the medullary pin 1. In a cross-sectional area 19, orthogonal to the longitudinal axis 17 of the medullary pin 1, the projection of the center of gravity of the tab 22 lies on a radius 21, which encloses an angle ~~β~~β of 45° with the projection 18'~~,~~ of the borehole axis 18 of the proximal transverse borehole 6 in this cross-sectional area 19. Viewed parallel to the longitudinal axis 17 of the medullary pin 1, the tab 22 envelopes the medullary pin 1 at an angle ~~α~~α which ranges from

155° to 165°. The petals 23, 24 end proximally with respect to the proximal transverse borehole 6. Furthermore, the bone plate 10, in its part that is transverse to the longitudinal axis 17 of the medullary pin 1, comprises a circular borehole 13, which is disposed coaxially with the longitudinal axis 17 and by means of which the bone plate 10 can be pushed over a corresponding circularly cylindrical elevation 9, which is provided at the proximal rear end 3 of the medullary pin 1. At its surface facing the proximal rear end 3 of the medullary pin 1, the bone plate 10 includes a cam 12, which can be lowered into a corresponding depression 14, which is provided at the proximal rear end 3 of the medullary pin 1. By these means, the bone plate 10 can be brought into a defined position relative to the medullary pin 1 and secured against rotation about the longitudinal axis 17 of the medullary pin 1. The bone plate 10 is immobilized at the proximal rear end 3 of the medullary pin 1 by means of a nut 40, the internal thread 41 of which can be screwed over a terminal external thread 15 provided at the circularly cylindrical elevation 9 at the rear end 3 at the medullary pin 1. [95]

~~Figure~~[96]FIG.[97] 3 shows a section of the distal half 4 of the medullary pin 1. The distal half 4 differs from the embodiment of the medullary pin 1 shown in [98]~~Fig~~[99]FIG[100]. 1 only therein that, instead of the distal transverse borehole 5, two transverse grooves 28, arranged in parallel, are provided. The transverse grooves 28 are disposed transversely to the longitudinal axis 17 of the medullary pin 1, extend parallel to a plane through the longitudinal axis 17 of the medullary pin 1 and the borehole axes 18[101],[102] and[103] 25 and partly accommodate locking screws 20 ([104]~~Fig~~[105]FIG[106]. 1.)[107]